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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION,	:	**Document Filed Electronically**
	:	
Plaintiff,	:	Civil Action No. 17- 06842-SDW-LDW
v.	:	
	:	Susan D. Wigenton, U.S.D.J.
LOTUS PHARMACEUTICAL CO., LTD. and	:	Leda Dunn Wettre, U.S.M.J.
ALVOGEN PINE BROOK LLC,	:	
	:	
Defendants.	x	

LOTUS PHARMACEUTICAL CO., LTD. AND ALVOGEN PINE BROOK LLC'S MOTION FOR JUDGMENT ON THE PLEADINGS

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Defendants Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook LLC (collectively "Defendants") respectfully move for judgment on the pleadings for Counts II, III, IV, IX, and XII in above-captioned action filed by Celgene Corporation ("Plaintiff" or "Celgene") pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. Judgment should be granted because the patent claims asserted by Plaintiff are invalid under 35 U.S.C. § 101, as they are directed to the abstract idea of restricting access to pharmaceuticals by patients who may be harmed by the drug, and therefore fail to claim patentable subject matter.

I. PRELIMINARY STATEMENT

The Supreme Court has long held that "laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (internal quotation marks and citations omitted). Such exceptions to patentability were deemed necessary to prevent monopolization of "the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). One cannot convert an otherwise abstract idea into a patent-eligible application simply by implementing the idea using a "generic computer." *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2357-58 (2014).

The patents asserted by Plaintiff in Counts II, III, IV, IX, and XII — U.S. Patent Nos. 6,315,720; 6,561,977; 6,755,784; 8,315,886; and 8,626,531 (the "REMS Patents"[1]) — fall precisely within this category. These patents claim the patent-ineligible abstract idea of restricting access to a pharmaceutical by patients who may be harmed by the drug, a well-known concept routinely implemented by doctors or pharmacists in the responsible performance of their duties. In this case, Plaintiff contends that these patents cover the Risk Evaluation and Mitigation Strategy ("REMS") that the FDA mandates to prevent the administration of Plaintiff's Revlimid®

[1]The REMS Patents are attached as Exhibits B, C, D, I, and L, respectively, to Celgene's complaint. (Dkt.1.)

product to pregnant patients. Plaintiff has also asserted these patents to prevent generic competition for its Thalomid®[2] and Pomalyst®[3] products.

Plaintiff attempted to dress up its claims by including references to "computer readable storage medium" and a "prescription approval code," but the patents describe no new technology or improvement to computer functionality. In fact, every step in each of the claims could be performed by a health care professional equipped with only a pen and paper. *See, e.g., Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372 (Fed. Cir. 2011) (stating that when each claim step "can be performed in the human mind, or by a human using a pen and paper," it is a clear indicator that the claim is directed to an "unpatentable mental process[]"). Following *Alice*, simply reciting an abstract idea with directions to "apply it with a computer," as Plaintiff attempts, does not transform the abstract idea into a patent-eligible invention. *Alice*, 134 S. Ct. at 2358.

Because the REMS Patents claim nothing more than an idea disembodied from any concrete technological improvement, the patents are abstract and thus invalid as a matter of law under 35 U.S.C. § 101. The REMS Patents represent nearly a third of the patents asserted by Plaintiffs. None of the inventors on the REMS Patents are listed as an inventor on any other asserted patents, and the REMS Patents have distinct issues of validity and infringement. Resolving the non-patentability of the REMS Patents now will greatly simplify matters for the parties and the Court going forward. Therefore, the court should grant Defendant's motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c).

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[2] *See, e.g., Celgene Corp. v. Lannett Holdings, Inc.*, No. 2:15-cv-00697 (D.N.J.); *see also* Orange Book listing for Thalomid®, *available at* https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=020785&Appl_type=N.

[3] *See, e.g., Celgene Corp. v. Hetero Labs Ltd.*, No. 2:17-cv-03387 (D.N.J.); *see also* Orange Book listing for Pomalyst®, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=204026&Appl_type=N.

II. BACKGROUND

The REMS Patents are part of the same patent family and all claim priority to the same October 2000 patent application. The patents have essentially identical specifications. The specifications disclose "methods for the delivery of drugs known or suspected of causing an adverse side effect." (*See, e.g.*, '977 Patent 3:36-38.[4]) The specifications disclose that prescribers and pharmacies can register in a "computer readable storage medium" by sending a registration card or form by mail, fax, on-line transmission, or over the telephone. (*Id.* 4:47-5:64.) Patients may be registered in a similar manner. (*Id.* 5:65-6:33.) The specifications further disclose that the prescriber counsels the patient, such as by, "in preferred embodiments," providing "the patient with literature materials on the drug for which a prescription is contemplated." (*Id.* 9:1-5.) For teratogenic drugs, *i.e.*, those that may cause birth defects, the specifications disclose counseling patients that the drugs should not be taken by pregnant women and that birth control should be used. (*Id.* 9:18-10:5.) The specifications disclose that prior to filling a prescription, the pharmacy "preferably" confirms by telephone or on-line transmission that "the patient has been registered and is eligible to receive the drug." (*Id.* 13:6-10.) The specifications disclose that "in certain embodiments," the pharmacy may consult the "computer readable medium to retrieve a prescription approval code" that is "preferably not provided unless the prescriber, the pharmacy, the patient, the patient's risk group and the patient's informed consent have been properly registered in the storage medium." (*Id.* 13:45-52.)

Nowhere do the specifications disclose any new or improved computer hardware or software. Nor do the specifications disclose any algorithms or other methods to improve the functionality of computers or other technology. Indeed, with regard to computer technology, the

[4]For convenience, citations are to the specification of the '977 Patent. Each of the other REMS Patents have equivalent disclosures.

specifications only teach that "[s]uitable computer readable storage media . . . will be apparent to one of ordinary skill in the art, once armed with the teachings of the present application." (*Id*. 5:15-20.)

Further, the REMS Patents themselves admit that the alleged technical terms in the claims, such as using a computer readable storage medium to ensure that a patient is approved to receive a drug, are not new. For example, they disclose prior art U.S. Patent No. 6,045,501, which according to the REMS Patents:

> [P]rovides methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug. According to the methods of this patent, prescriptions for the drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in the medium and qualified to prescribe the drug, that the pharmacy is registered in the medium and qualified to fill the prescription for the drug, and the patient is registered in the medium and approved to receive the drug.

(*Id*. 2:1-11.)

III. THIS MOTION IS RIPE FOR DETERMINATION

As instructed by the Court, Defendants did not file this motion before being granted leave. (*See* Dkt.36.) Following letter briefing by the parties (Dkts.34, 41, 44, 47, 55, 56), the Court granted Defendants leave to file this motion during a March 16, 2018 telephone conference. As explained in more detail in Defendants' letter briefs, this motion is ripe for determination because there are no factual or claim construction disputes that preclude determination. Indeed, Defendants waited to file this motion until the lack of such disputes was confirmed by the parties' exchange of contentions regarding invalidity and proposed terms for claim construction.

Patent eligibility is a "threshold test." *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). As such, the Federal Circuit has repeatedly endorsed Rule 12 judgments, at the pleadings stage, that patents are invalid under § 101. *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics*

LLC, 859 F.3d 1352, 1360 (Fed. Cir. 2017) (collecting cases). Similarly, this district has found it appropriate to invalidate patents under § 101 at the pleadings stage, including in ANDA cases such as this one. *See, e.g.*, *Scibetta v. Slingo, Inc.*, No. CV 16-8175, 2018 WL 466224, at *16 (D.N.J. Jan. 17, 2018); *Boehringer Ingelheim Pharms., Inc. v. HEC Pharm Co.*, No. CV 15-5982, 2016 WL 7177704, at *13 (D.N.J. Dec. 8, 2016); *Wireless Media Innovations, LLC v. Maher Terminals, LLC*, 100 F. Supp. 3d 405, 417 (D.N.J. 2015), *aff'd*, 636 F. App'x 1014 (Fed. Cir. 2016); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, No. CV 12-2501, 2013 WL 3964909, at *14 (D.N.J. July 31, 2013), *aff'd*, 776 F.3d 1343 (Fed. Cir. 2014).

Judge Mayer of the Federal Circuit has recognized that "addressing section 101 at the outset of litigation [has] a number of salutary effects," including "conserv[ing] scarce judicial resources," "provid[ing] a bulwark against vexatious infringement suits," and "most importantly, . . . protect[ing] the public" by "weeding out those patents that stifle innovation and transgress the public domain." *Ultramercial v. Hulu, LLC*, 772 F.3d 709, 718-19 (Fed. Cir. 2014) (Mayer, J., concurring). Furthermore, Rule 12 judgments under § 101 may prevent unnecessary discovery, claim construction, and motion practice. This is especially true where, as here, a Rule 12 judgment under § 101 at the pleadings stage would remove a significant number of patents from the case.

Despite filing three letters opposing this motion, Celgene has yet to identify any concrete claim construction dispute that would preclude determination of this motion at this time. Celgene has recently proposed four terms in the claims of the REMS Patents for construction — "computer readable storage medium," "prescription approval code," "[patient] risk groups," and "retrieved." However, none of these terms — under any construction — make the claims any less abstract or add

an inventive concept. Celgene has not explained how the construction of any of these terms would affect the determination of this motion despite the opportunity to do so in its letters.

Indeed, "claim construction is not an inviolable prerequisite to a validity determination under § 101," especially, whereas here, the "basic character of the claimed subject matter" in dispute in this action is clearly evident. *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d. 1343 (Fed. Cir. 2014) ("*Content Extraction*") (quoting *Ultramercial*, 772 F.3d at 714-15; *Bancorp Servs. LLC v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1278 (Fed. Cir. 2012)). As explained below, there is no plausible construction of "computer readable storage medium" that can transform it from a generic computing device. Nor can any plausible construction of "[patient] risk groups" result in the related claim limitation being anything more than collecting and categorizing data. Furthermore, Defendants have agreed, for this motion, to adopt Celgene's construction of "prescription approval code," the only term that Celgene told the Patent Trial and Appeal Board ("PTAB") needed construction during an *inter partes* review of the '720 patent. *See, e.g., Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01096, Paper No. 41, at 21-22 (PTAB Feb. 12, 2016). But, as explained below, this construction also does not save the claims.

Celgene also argued in its letters that there are factual issues regarding the term "prescription approval code," the term "computer readable storage medium," and the degree to which the claims preempt use of the underlying abstract idea. (*See* Dkt.56, at 2-3.) But Celgene has presented no such evidence of any factual dispute and simply asserted that it will present evidence only after fact and expert discovery have closed. (*See id*. at 2.) Further, while the claims impermissibly preempt the abstract idea of restricting access to pharmaceuticals by patients who may be harmed by the drug, a dispute as to the exact degree of that preemption does not bar

granting this motion because even limited preemption cannot save abstract claims. *See, e.g.*, *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362-63 (Fed. Cir. 2015) ("[T]hat the claims do not preempt all price optimization or may be limited to price optimization in the e-commerce setting do not make them any less abstract.").

Moreover, this case is unlike those in which the Federal Circuit found invalidity findings under § 101 to be inappropriate at summary judgment or the motion to dismiss stage. For example, in *Berkheimer*, the Federal Circuit affirmed the district court's grant of summary judgment that certain claims were invalid under § 101 but vacated the grant regarding certain dependent claims because the specification's disclosure created factual questions under *Alice* step two as to whether "[t]hese claims recite a specific method of archiving that . . . provides benefits that improve computer functionality." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370-71 (Fed Cir. 2018). Unlike the patent in *Berkheimer*, however, the specifications of the REMS Patents create no factual questions as to whether the claims recite improved computer functionality.

Instead, these patents only concern improvements to human activities that are not patentable. *See, e.g.*, *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1324 (Fed. Cir. 2016) (finding claims invalid where the steps of the claims "could all be performed by humans without a computer"). More specifically, the REMS Patents teach that the purported improvements of the claimed invention are "to minimize and simplify the demands on the pharmacy, thereby improving compliance with the system of distribution, and reducing the risk that the drug will be dispensed to a contraindicated individual," and to "educate men and women about the risk of teratogenic drugs, such as thalidomide." ('977 Patent 2:11-15, 2:40-42.) None of these disclosures concern improvements in technology. Therefore, because there exist no

specific questions of fact as to whether the asserted claims of the REMS Patents contain a transformative inventive concept relating to improving computer functionality, a finding that the patents are invalid under § 101 at this stage is appropriate under *Berkheimer*.

In *Aatrix*, the Federal Circuit reversed the district court's denial of leave for the patentee to file a second amended complaint because there were "factual allegations in the second amended complaint, which when accepted as true, prevent dismissal pursuant to Rule 12(b)(6)." *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1130 (Fed. Cir. 2018).[5] More specifically, the amended complaint included concrete allegations suggesting "the claimed invention is directed to an improvement in the computer technology itself." *Id.* at 1127. As discussed above, however, Celgene has not — and cannot — allege that claimed subject matter in the REMS Patents results in any improvements in the computer technology itself. Celgene's complaint provides no allegations of such improvements. (*See, e.g.*, Dkt.1 ¶¶ 8-23 (listing only the issue dates, titles, and names of the patents-in-suit).) Therefore, there are no factual allegations that prevent the Court from deciding Defendants' proposed motion under *Aatrix*.

For all of these reasons, this Court should decide Defendants' § 101 motion at this stage.

IV. LEGAL STANDARD

A. Subject Matter Eligibility Is a Threshold Question Appropriately Considered at The Motion to Dismiss Stage

Under Rule 12(c) of the Federal Rules of Civil Procedure, a party may move for judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." Fed. R. Civ. P. 12(c). "A motion for judgment on the pleadings is 'functionally identical' to a Rule 12(b)(6) motion to dismiss for failure to state a claim." *Boehringer*, 2016 WL 7177704,

[5] The Federal Circuit also vacated the district court's dismissal under Rule 12(b)(6) because the district court incorrectly found that the data processing system claims at issue were directed to an intangible embodiment. *Aatrix*, 882 F.3d at 1123. This holding is also inapplicable here as Defendants do not rely on the "intangible embodiment" case law.

a *4 (quoting *Cave Consulting Grp., Inc. v. Truven Health Analytics, Inc.*, No. 15-cv-02177-SI, 2016 WL 283478, at *1 (N.D. Cal. Jan. 25, 2016)). In deciding such a motion, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

Patent eligibility under 35 U.S.C. § 101 is "an issue of law." *See Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1340-41 (Fed. Cir. 2013); *see also Bilski*, 561 U.S. at 602 (describing patent eligibility under 35 U.S.C. § 101 as "a threshold test"). As explained above, the Federal Circuit has repeatedly affirmed judgments pursuant to Rule 12 that patents are invalid under §101, and this district has issued such judgments. And for good reason — such judgments have the potential to conserve judicial resources and narrow the issues in the case by, for example, significantly reducing the number of patents at issue.

B. The Supreme Court's Seminal *Alice* Decision Sets Forth A Two-Part Test For Subject Matter Eligibility Under 35 U.S.C. § 101

In order to determine patent eligibility under 35 U.S.C. § 101, courts apply the now familiar two-step framework established in *Alice* and *Mayo*. First, a court must "determine whether the claims at issue are directed to a patent-ineligible concept" such as an abstract idea. *Alice*, 134 S. Ct. at 2355. To determine whether a patent is directed to an abstract idea, the court must first "ascertain[] the basic character of the subject matter," *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1348 (Fed. Cir. 2015), and then determine "whether [this] character . . . is directed to excluded subject matter." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting *Internet Patents*, 790 F.3d at 1346).

If the court finds that the claims are directed to an abstract idea, it then proceeds to the second step of the *Alice* framework, where it must "determine whether [these claims] contain[]

an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 134 S. Ct. at 2357 (citations omitted). The use of a "generic computer" cannot, by itself, supply this "inventive concept." *Id.* at 2358.

V. ARGUMENT

A. Celgene's REMS Patents Can Be Analyzed Based On Three Representative Claims

In cases involving multiple similar patents and claims, such as this, a court need not conduct a detailed analysis of every asserted claim. Instead, the court may rely on representative claims that are "substantially similar and linked to the same abstract idea" as the remaining claims. *Content Extraction*, 776 F.3d at 1348 (affirming invalidation of four patents containing a total of 242 claims on the basis of only two representative claims). This is particularly true when, as here, the asserted patents belong to the same patent family, involve the same technology, and share essentially identical patent specifications. *See, e.g.*, *Alice*, 134 S. Ct. at 2359 (invalidated claims from multiple patents based on a single representative claim). The REMS Patents are all directed to the same abstract idea of restricting access to pharmaceuticals by patients who may be harmed by them. However, due to nuances in the language and formatting used for the claims, the patents are most easily characterized by three representative claims, as discussed below.

B. The Drug Delivery Patents Are Invalid For Claiming A Patent-Ineligible Abstract Idea

Independent claim 1 of the '977 Patent is representative of the '720, '977, and '784 Patents (collectively the "Drug Delivery Patents"), which are directed to methods of delivering drugs to patients[6]:

> 1. A method for delivering a drug to patients in need of the drug while restricting access to the drug by patients for whom the drug may be contraindicated, said method comprising permitting prescriptions for the drug to be filled by a pharmacy only after

[6] The independent claims of the '720 and '784 Patents are substantially similar — and, in fact, nearly identical — to claim 1 of the '977 Patent, as shown in the charts attached as Exhibit A.

> the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium, wherein generation of the prescription approval code comprises the following steps:
>
> a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for the drug;
>
> b. defining a set of information to be obtained from a patient, which information is probative of the risk that an adverse side effect is likely to occur if the drug is taken by the patient;
>
> c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment in the medium;
>
> d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and
>
> e. upon a determination that the risk is acceptable, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled.

C. The Drug Delivery Patents Are Directed To The Abstract Idea Of Restricting Access To Pharmaceuticals By Patients Who May Be Harmed By The Drug

The first step of the *Alice* test requires the court to look to the "basic character" of the claims to determine whether the patents are directed to an abstract idea (or a law of nature or natural phenomenon). *See Internet Patents*, 790 F.3d at 1348. Here, the claims of the Drug Delivery Patents are directed to methods of restricting access to a pharmaceutical by patients who may be harmed by the drug, *i.e.*, patients at risk for adverse side effects.

The claims themselves support this characterization. For example, the representative claim is "[a] method for delivering a drug to patients in need of the drug while restricting access to the drug by patients for whom the drug may be contraindicated." ('977 Patent cl.1.) This concept of restricting access to prescription drugs based on the risk of adverse side effects is, and historically has been, a fundamental concept in the practice of medicine and pharmacy. Thus, restricting access to prescription drugs to protect patient safety is "a method of organizing human activity" and, therefore, "an 'abstract idea' beyond the scope of § 101." *Alice*, 132 S. Ct. at 2356.

That the Drug Delivery Patent claims are directed to an abstract idea is further demonstrated by the nature of the individual steps of the claimed methods. When analyzed limitation by limitation and as an ordered combination, the claimed methods are clearly directed to the basic steps of collecting, categorizing, and analyzing data related to restricting access to a pharmaceutical by patients who may be harmed by the drug. (*See* Exh. A.) For example, the representative claim for the Drug Delivery Patents involves the steps of: (a) defining categories of patient "risk groups" based on known risk information about a drug (*i.e.*, "collecting and categorizing data"); (b) identifying and collecting patient information relevant to the risk groups (*i.e.*, "collecting data"); (c) assigning the patient to one or more risk groups based on the patient data (*i.e.*, "recognizing and categorizing data"); (d) using the categorized information to determine whether risks to the patient are acceptable (*i.e.*, "analyzing data"); and (e) generating a prescription approval code in the event the risk is determined to be acceptable (*i.e.*, "generating and displaying new data" based on the analysis).

The Federal Circuit has repeatedly held that the collection, categorization, and storage of data (as in the claims of the Drug Delivery Patents) are abstract ideas that are patent ineligible under § 101. *See, e.g.*, *Smart Sys. Innovations, LLC v. Chicago Transit Auth.*, 873 F.3d 1364, 1372 (Fed. Cir. 2017) ("We have determined that claims directed to the collection, storage, and recognition of data are directed to an abstract idea.") (citing *Content Extraction*, 776 F.3d at 1347 (finding directed to "collecting data," "recognizing certain data within the collected data set," and "storing the recognized data in memory" fall under *Alice* step one)); *see also In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016) (finding claims "directed to the abstract idea of classifying and storing digital images in an organized manner.")

Similarly, the Federal Circuit has "treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category." *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016); *see also Cybersource*, 654 F.3d at 1372 (stating that a clear indicator that a claim is directed to "unpatentable mental processes" is where all of the claim's steps "can be performed in the human mind, or by a human using a pen and paper").

Presenting the results of the analysis via a prescription approval code, as recited in the claims of the Drug Delivery Patents, does not render the claims any less abstract. *See, e.g.*, *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 910 (Fed. Cir. 2017) ("The fact that an identifier can be used to make a process more efficient, however, does not necessarily render an abstract idea less abstract."). According to the Federal Circuit, "merely presenting the results of abstract processes of collecting and analyzing information, without more . . . is abstract as an ancillary part of such collection and analysis." *Elec. Power Grp.*, 830 F.3d at 1354. Therefore, the analysis of patient and drug data to generate new data (*i.e.*, the determination of whether a risk to the patient is acceptable) and the presentation of the results of that data analysis (*i.e.*, the generation and display of a prescription approval code) clearly fall within the realm of abstract ideas.[7]

Additionally, the use of a "computer readable storage medium" in the performance of the claimed methods also does not render the abstract ideas patent eligible. As the Federal Circuit

[7] Celgene has also argued that it "will present evidence throughout this case that the claims of the REMS Patents are directed to specific methods of treatment that employ a technological solution to a problem, at least through the presence of the claimed 'prescription approval code.'" (ECF No. 41, at 4.) But Celgene's argument is essentially the same as that rejected by the court in *Berkheimer*. As in *Berkheimer*, simply limiting the claimed invention of the REMS Patents to "a technological solution" would not "make an abstract concept any less abstract under step one." *See Berkheimer*, 881 F.3d at 1367.

has repeatedly held, "[s]imply adding a 'computer aided' limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible." *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2012); *see also Bancorp*, 687 F.3d at 1278 ("[T]he use of a computer in an otherwise patent-ineligible process for no more than its most basic function—making calculations or computations—fails to circumvent the prohibition against patenting abstract ideas and mental processes.").

The determination of whether a claim is directed to an abstract idea can also be accomplished by comparing the claims at issue to those that have already been found to be directed to abstract ideas in previous cases. *See Enfish*, 822 F.3d at 1334. The claims at issue here are abstract and unpatentable for the same reasons as those at issue in *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x. 950 (Fed. Cir. 2014). There, the Federal Circuit held that patent claims directed to methods for "guiding the selection of a therapeutic treatment regimen for a patient" were unpatentable abstract ideas. *Id*. at 955. The representative claim in that case read as follows:

> 1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:
>
> (a) providing patient information to a computing device comprising:
>
> a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
>
> a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
>
> a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and
>
> (b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and

> (c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

Id. at 951-52. Like the claims of the Drug Delivery Patents, the representative claim in *SmartGene* involved the collection and categorization of information relating to patients and potential therapies, the analysis of said information to generate new data regarding potential treatment(s) for the patient, and the generation and display of the results of the analysis. As with the Drug Delivery Patents, the claims in *SmartGene* included the use of a "computing device" or, in some claims, a "computer usable storage medium" to accomplish the claimed steps. *Id.* at 952.

In *SmartGene*, the Federal Circuit affirmed the district court's holding that "the claim 1 method falls outside the eligibility standards of § 101 as that provision has been construed." *Id.* at 954. According to the Federal Circuit, "section 101 d[oes] not embrace a process defined simply as using a computer to perform a series of mental steps that people, aware of each step, can and regularly do perform in their heads." *Id.* The Federal Circuit held that "[w]hatever the boundaries of the 'abstract ideas' category, the claim at issue here involves a mental process excluded from § 101: the mental steps of comparing new and stored information and using rules to identify medical options." *Id.* at 955. That is the exact mental process claimed in the Drug Delivery Patents.

The Federal Circuit's description of the representative claim in *SmartGene* further highlights the similarities between the asserted claims of the Drug Delivery Patents are to those that were declared unpatentable in *SmartGene*:

> Claim 1 does no more than call on a 'computing device,' with basic functionality for comparing stored and input data and rules, to do what doctors do routinely. . . . Claim 1 places only very broad limitations on a 'computing device': it must contain—like a doctor's mind—a set of 'expert rules for evaluating and selecting' from a stored 'plurality of different therapeutic treatment regimens,' as well as 'advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens.'

Id. at 954-955.

Here, the claims of the Drug Delivery Patents do no more than call on a "computer readable storage medium," with basic functionality for comparing stored and input data and rules, to do what doctors and pharmacists do routinely—determining and communicating the acceptability of a drug for a patient with a given medical profile. There is no limitation placed on the computer readable storage medium, and in fact, the specification states that suitable computer readable storage media for use in the claimed methods "will be apparent to one of ordinary skill in the art," indicating that there is nothing unique or novel about the computer devices used in the claimed methods. '977 Patent, 5:15-20.

For the reasons stated above, the claims of the Drug Delivery Patents are directed to an abstract idea and therefore meet Step 1 of the *Alice* test.

VI. THE DRUG DELIVERY PATENTS LACK ANY "INVENTIVE CONCEPT" THAT TRANSFORMS THE ABSTRACT IDEA INTO PATENTABLE SUBJECT MATTER

Once the first step of the *Alice* analysis is met, the Court must then assess whether the elements of each claim, considered individually or as an ordered combination, contain some additional "inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application." *Alice*, 134 S. Ct. at 2357 (internal quotation marks and citations omitted). The Drug Delivery Patents contain no such "inventive concept" that would render them eligible for patent protection for at least three reasons: (1) the claims rely entirely on the use of a generic computer, which the Supreme Court made clear in *Alice*, "cannot transform a patent-ineligible abstract idea into a patent-eligible invention," *id.* at 2358; (2) the "prescription approval code" generated by the generic computer does not add an "inventive concept"; and (3) the claims fail the "machine-or-transformation" test because they are not tied to any particular machine and do not transform any physical article into a different thing.

A. Implementing an Abstract Idea on a Generic Computer Cannot Transform the Idea into a Patent Eligible Invention

As discussed above, the Drug Delivery Patents—which were all issued prior to the Supreme Court's seminal *Alice* opinion—merely use a computer to automate a task that is routinely manually performed by health care professionals. A generic computer is insufficient to supply the necessary "inventive concept" for patentability under *Alice*. *See id.* (stating that "the mere recitation of a generic computer" to perform an abstract idea automatically "cannot transform a patent-eligible abstract idea into a patent-eligible invention"); *see also Bancorp.*, 687 F.3d at 1278 ("[T]he use of a computer in an otherwise patent ineligible process for no more than its most basic function—making calculations or computations—fails to circumvent the prohibition against patenting abstract ideas and mental processes."); *Dealer*, 674 F.3d at 1333 ("Simply adding a 'computer aided' limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible.").

The computer components in the claims are "purely conventional" performing nothing more than basic tasks, such as the collecting, storing, categorizing, analyzing, generating, and displaying data, which are all "computer functions [that] are 'well-understood, routine, conventional activit[ies]' previously known to the industry." *Alice*, 134 S. Ct. at 2359 (quoting *Mayo*, 566 U.S. at 72). The specifications of the Drug Delivery Patents fail to describe any specific characteristics or improvements inherent in the computer devices used in the claimed methods. (*See, e.g.*, '977 Patent 5:15-20.) The Federal Circuit has made clear that such generic components "do not transform the claim, as a whole, into significantly more than a claim to the abstract idea itself." *Credit Acceptance Corp. v. Westlake Servs.*, 859 F.3d 1044, 1056 (Fed. Cir. 2017) (internal quotation marks and citations omitted); *see also Mortg. Grader*, 811 F.3d at 1324-25 (stating that "the claims 'add' only generic computer components such as an

'interface,' 'network,' and 'database' . . . [which] do not satisfy the inventive concept requirement").

The Drug Delivery Patents do not identify any benefit in the disclosed computer technology itself but instead assert that the inventive aspect of the claims is increased efficiency for a pharmacy. (*See, e.g.*, '977 Patent 2:11-15.) The Federal Circuit has, however, made clear that there is nothing inventive about using a computer for the sole purpose of doing something more quickly or increasing the efficiency of something a human would otherwise accomplish. *See, e.g.*, *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1370 (Fed. Cir. 2015) ("[O]ur precedent is clear that merely adding computer functionality to increase the speed or efficiency of the process does not confer patent eligibility on an otherwise abstract idea."); *MySpace, Inc. v. Graphon Corp.*, 672 F.3d 1250, 1267 (Fed. Cir. 2012) ("While running a particular process on a computer undeniably improves efficiency and accuracy, cloaking an otherwise abstract idea in the guise of a computer-implemented claim is insufficient to bring it within section 101."); *Bancorp*, 687 F.3d at 1278 ("[T]he fact that the required calculations could be performed more efficiently via a computer does not materially alter the patent eligibility of the claimed subject matter.").

Finally, the use of a computer in the Drug Delivery Patents' claims is factually distinguishable from those cases in which the Federal Circuit has sustained computer implementation claims under § 101. For example, in *Enfish*, the court held that claims directed to a self-referential table for a computer database were not abstract because they corresponded to "an improvement in the functioning of a computer" itself. *Enfish*, 822 F.3d at 1338. Similarly, the Federal Circuit in *DDR Holdings* held that the claims at issue were not invalid for claiming abstract subject matter because they were "necessarily rooted in computer technology in order to

overcome a problem specifically arising in the realm of computer networks." *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014). In contrast, the Drug Delivery Patents' claims are not directed to computer technology and do nothing to improve the functioning of the computer itself; instead, they "simply add[] conventional computer components to well-known business practices" and are therefore not patent eligible. *Enfish*, 822 F.3d at 1338.

B. The Claimed "Prescription Approval Code" Is Itself Abstract

The inclusion of the "prescription approval code" in the claims of the Drug Delivery Patents is insufficient to render an abstract idea patentable because the code is itself abstract. Regarding the approval code, the specifications explain that:

> In certain embodiments of the invention, the methods may require that the registered pharmacy consult the computer readable medium to retrieve a prescription approval code before dispensing the drug to the patient. This approval code is preferably not provided unless the prescriber, the pharmacy, the patient, the patient's risk group and the patient's informed consent have been properly registered in the storage medium.

('977 Patent 13:45-52.) In an *inter partes* review for the '720 Patent, Celgene asserted that the term "prescription approval code" should be construed to mean:

> [A] code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable.

Coalition for Affordable Drugs VI LLC v. Celgene Corp., IPR2015-01096, Paper 73, at 12-13 (P.T.A.B. Oct. 26, 2016). The P.T.A.B. adopted Celgene's construction and explained that "an approval code may be an identifier, such as an approval code identifier used in consumer credit card transactions (approved/declined)." *Id*. at 15.[8]

[8] For purposes of this motion, Defendants will utilize Celgene's construction of "prescription approval code" from the *inter partes* review.

Under Celgene's construction, the "prescription approval code" is simply an identifier of the outcome of the other abstract processes of the claims, *e.g.*, "approved" or "declined." Indeed, the code is itself abstract and akin to the "unique identifier" addressed by the Federal Circuit in *Secured Mail*, where the patentee argued that the claims were directed to affixing a "unique identifier" to mail items to improve existing processes. *Secured Mail*, 873 F.3d at 910. The Federal Circuit held that the claims were directed to an abstract idea and that the patent did not describe any "special rules or details of the computers, databases, printers, or scanners." *Id.* The Federal Circuit also explained that the patent did not describe how the unique identifier is generated or how it differs from information such as names and addresses typically affixed to mailed items. *Id*.

As with the identifier in the *Secured Mail* patents, the REMS Patents provide no special rules or details of computer systems for the prescription approval code. Nor do they describe how the code is generated or explain how it is different than identifiers, such as a prescriber's signature, that are conventionally used to indicate that "an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable." Because identifiers that an affirmative risk assessment has been made, such as a prescriber's signature, are well-known, routine, and conventional, the prescription approval code cannot serve as an inventive concept sufficient to save the claims of the Drug Delivery Patents. The fact that the claims require that the prescription approval code be generated by a computer rather than a prescriber is of no importance to the § 101 analysis because, as discussed above, neither the claims nor the patent describe any technology used to generate such a code that is not purely conventional and well understood by those in the industry.

C. The Drug Delivery Patents Fail the Machine-or-Transformation Test, Further Indicating That They Are Patent-Ineligible

The Federal Circuit has stated that while not definitive, "the machine-or-transformation test . . . can provide a 'useful clue' in the second step of the *Alice* framework." *Ultramercial*, 772 F.3d at 716 (citations omitted). According to this test, a claim may be patent-eligible under § 101 if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.* The Drug Delivery Patents fail both prongs of the test, further indicating that they are directed to patent-ineligible subject matter.

First, the Drug Delivery Patents are not tied to a particular machine. Instead, they rely on a generic "computer readable storage medium." (*See, e.g.*, '977 Patent cl.1.) As the Federal Circuit has held, claims that "are not tied to any particularly novel machine or apparatus, only a general-purpose computer," do not meet the machine prong of the machine-or-transformation test. *Ultramercial*, 722 F.3d at 716; *see also CyberSource*, 654 F.3d at 1375 ("[M]erely claiming a software implementation of a purely mental process that could otherwise be performed without the use of a computer does not satisfy the machine prong of the machine-or-transformation test.").

Second, the Drug Delivery Patents do not transform any physical object or article into a different state. Instead, they merely involve the collection and analysis of patient information—a process fundamental to the relationship that exists among patients and their doctors/pharmacists as part of the process of prescribing medication. *See, e.g.*, *Ultramercial*, 772 F.3d at 717 ("[M]anipulations of 'public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances.'" (quoting *In re Bilski*, 545 F.3d 943, 963 (Fed. Cir. 2008) (en banc)). While the Drug Delivery Patents do result in the generation

of a prescription approval code, "[a]ny transformation [of data] from the use of computers or the transfer of content between computers is merely what computers do and does not change the analysis." *Ultramercial*, 722 F.3d at 717; *see also CyberSource*, 645 F.3d at 1375 (stating that "mere manipulation or reorganization of data . . . does not satisfy the transformation prong" of the machine-or-transformation test). Therefore, as in *Ultramercial*, the Drug Delivery Patents "do not transform any article to a different state or thing," and thus do not meet the transformation prong of the machine-or-transformation test. *Id.*, 722 F.3d at 717.

For all of these reasons, the claims of the Drug Delivery Patent fail to satisfy *Alice* Step 2 and are invalid.

VII. ADDITIONAL ASSERTED CLAIMS OF THE DRUG DELIVERY PATENTS ARE ALSO PATENT INELIGIBLE

The other asserted claims of the Drug Delivery Patents also fail to add meaningful limitations that remove the claims from the realm of abstract ideas or impart an inventive concept. As with the representative claim, the other claims of the Drug Delivery Patents do not provide a technological improvement that confers patentability into the abstract idea of restricting access to pharmaceuticals by patients who may be harmed by the drug.

Nor does any of these claims supply an inventive concept. Although the other claims introduce new limitations that narrow the scope of the representative claim, many of these claims merely recite the use of existing technology—such as transmission by facsimile, interpretation by optical character recognition software, and conducting a survey telephonically using an integrated voice recognition software—"to perform well-understood, routine, and conventional activities." The use of such generical computer components to perform routine activities does not supply an "inventive concept" to these claims. *See Content Extraction*, 776 F.3d at 1348 (holding that the use of a generic scanner did not constitute an "inventive concept"); *see also Internet*

Patents, 790 F.3d at 1349 (stating that additional limitations of dependent claims simply representing "generic data collection steps" "do not add an inventive concept").

Other claims require diagnostic testing, but such claims without more are also unpatentable. *See, e.g.*, *Mayo*, 566 U.S. at 79 (finding claims to be unpatentable despite the inclusion of diagnostic steps); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1371 (Fed. Cir.), *cert. denied*, 137 S. Ct. 242 (2016) (affirming motion to dismiss and finding claims directed to methods of analyzing sequences of genomic DNA invalid under § 101); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015) (finding claims directed to methods of detecting fetal DNA to be unpatentable).

A. <u>The '886 Patent Is Invalid For Claiming A Patent-Ineligible Abstract Idea</u>

The '886 Patent is also directed to the same abstract idea, but the claims focus specifically on the restricting of access to teratogenic drugs by male patients. (*Compare* Exh. A *with* Exh. B.) Since the risk associated with such situations is that the male patient will expose a fetus carried by his sexual partner to the drug, the method of the '886 Patent is directed toward warning the patient of this risk and recording his acknowledgment of these warnings prior to dispensing the medication. Accordingly, the '886 Patent is more simply analyzed based on its own representative claim. Claim 1, the single independent claim of the '886 Patent, is a representative:

> 1. A method of treating a male patient having a disease or condition responsive to a teratogenic drug comprising permitting prescriptions for the drug to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription, wherein the generation of the prescription approval code comprises the following steps:
>
> (a) via a computer readable storage medium, registering a prescriber and the pharmacy with a distributor of a teratogenic drug;
>
> (b) determining whether the patient is able to understand and carry out instructions;

> (c) upon determination that the patient is able to carry out the instructions, providing verbal and written warnings of the hazard of taking the drug and exposing fetus to the drug;
>
> (d) further providing verbal and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;
>
> (e) obtaining acknowledgement of said warnings from the patient;
>
> (f) via a computer readable storage medium, registering the patient with the distributor; and
>
> (g) upon obtaining the acknowledgement and registrations, generating via a computer readable storage medium the prescription approval code to be retrieved by the pharmacy before the prescription is filled; and
>
> (h) upon retrieving a prescription approval code, administering the drug to the patient.

The steps of representative claim 1 consist of: (1) **collecting information**, both in the form of the patient's acknowledgments of the risks associated with the drug as well as prescriber, pharmacy, and patient registration information; and (2) **generating a result** in the form of a prescription approval code. As with the Drug Delivery Patents, each claim step can be performed by a health care professional with nothing but a pen and paper, and therefore, the claims are directed to an abstract idea. *See Cybersource*, 654 F.3d at 1372. Further, the limitations directed to collecting information and generating a result are abstract, whether taken individually or as an ordered combination.

Like the claims of the Drug Delivery Patents, the claims of the '886 Patent lack "an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application." *Alice*, 134 S. Ct. at 2357 (internal quotation marks and citations omitted). The claims recite the same generic "computer readable storage medium" and "prescription approval code" as in the Drug Delivery Patents. But as explained above, such generic computer components and abstract codes cannot confer patentability on abstract claims. No other

limitation in the representative claim of the ’886 Patent even remotely provides an inventive concept. Nor does the ordered combination of the claim steps.

The dependent claims of the ’886 Patent likewise fail to remove the claims from the realm of an abstract idea or impart an inventive concept. As with claim 1, many of the dependent claims can be performed by a health care professional using a pen and paper. Furthermore, the dependent claims rely on the same generic “computer readable storage medium” without adding any inventive concept.

Thus, the claims of the ’886 Patent are invalid because they claim unpatentable subject matter.

B. The ’531 Patent Is Invalid For Claiming A Patent-Ineligible Abstract Idea

The claims of the ’531 Patent are reconfigured to focus on a system and method of communicating information to a pharmacist but ultimately are directed to the same abstract idea as the other patents. Independent claim 1 of the ’531 Patent is representative[9]:

> 1. A system for communicating over a network with a pharmacist for authorizing delivery of a contraindicated drug to a patient, the patient pre-assigned to at least one risk group of a plurality of risk groups, the plurality of risk groups defined based on factors which indicate one or more risks of one or more adverse side effects if the patient receives the drug, the system comprising:
>
> a computer device including:
>
> a computer readable medium having stored therein the plurality of risk groups, the at least one risk group assignment, and registration information of the patient;
>
> the computer device configured to provide:

[9] Claim 21, the only other independent of the ’531 Patent, simply recasts the abstract idea of claim 1 as a “method for communicating over a network.” (*See* Exh. C.) It does not anything of import to the § 101 analysis. *Accenture*, 728 F.3d at 1344 (“Because the system claim and method claim contain only minor differences in terminology but require performance of the same basic process, they should rise or fall together.” (quotations omitted)).

> an interface configured to receive an on-line transmission of a pharmacist prescription for the patient in order to dispense the contraindicated drug to the patient;
>
> a generator configured to generate a prescription approval code based on comparison of the on-line transmission of the pharmacist prescription for the patient with the registration information of the patient stored in the computer readable medium to confirm if the patient is registered, and based on comparison of the on-line transmission of the pharmacist prescription for the patient with the risk group assignment stored in the computer readable medium to determine if the patient is eligible to receive the contraindicated drug, such that the risk group assignment is based on a predefined set of risk parameters for the contraindicated drug; and
>
> an interface configured to send an on-line transmission to the pharmacist including the generated prescription approval code when the registered patient is eligible to receive the drug;
>
> wherein the pharmacist can proceed with dispensation of the drug to the patient on the basis of the generated prescription approval code once received.

Similarly to the Drug Delivery Patents, the ’531 Patent involves: (a) defining categories of patient “risk groups” and identifying and collecting patient information relevant to the risk groups (*i.e.*, “collecting and categorizing data”); (b) transmitting a prescription (*i.e.*, “transmitting data”); (c) comparing the prescription information with the risk group assignment (*i.e.*, “analyzing data”); and (d) generating and transmitting a prescription approval code in the event the risk is determined to be acceptable (*i.e.*, “generating and displaying new data” based on the analysis). (*Compare* Exh. A *with* Exh, C.) It merely recasts these elements in terms of the generic computer components that perform these tasks.

But recasting abstract ideas as systems by “graft[ing] generic computer components onto otherwise-ineligible method claims” cannot save the claims of the ’531 Patent. *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1096 (Fed. Cir. 2016). As with the claims in *Alice*, “the system claims are no different from the method claims [of the Drug Delivery Patents] in substance.” *Alice*, 134 S. Ct. at 2360. “The method claims recite the abstract idea implemented

on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea." *Id.*; s*ee also Accenture Glob. Servs.*, 728 F.3d at 1344; *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005, 1007 (Fed. Cir. 2014) ("[T]here is no meaningful distinction between the method and system claims . . . " because "[t]he system claims recite the same basic process as the method claims . . . .").

The claims of the '531 Patent recite only generic computer components such as a "computer device," a "computer readable storage medium," "a generator," and "interface[s]" for receiving and sending transmission, which are purely conventional and rely on computer components well known in the industry. Indeed, the specification of the '531 Patent is utterly void of any details regarding these components—entirely failing to mention the computer device, the generator, or the interfaces apart from in the claims themselves. And with regard to the computer readable storage medium, it explains only that "[s]uitable computer readable storage media" will be "apparent to one of ordinary skill in the art . . . ." ('531 Patent 5:26-30.) The specification's complete failure to even mention a "computer device," "generator," or "interface" is a clear indicator that these components are generic computer technology that perform routine functions. *See, e.g.*, *Affinity Labs of Tex.s, LLC v. Amazon.com Inc.*, 838 F.3d 1266, 1269 (Fed. Cir. 2016) (finding claims to wireless streaming to mobile devices patent ineligible where "[t]he patent does not disclose any particular mechanism for wirelessly streaming content to a handheld device.").

The Supreme Court and the Federal Circuit have repeatedly held that such generic components cannot save otherwise abstract claims. *See Alice*, 134 S. Ct. at 2360 (finding claims requiring a "computer readable medium" invalid under Section 101); *FairWarning*, 839 F.3d at 1096 ("As we have explained, the use of generic computer elements like a microprocessor or

user interface do not alone transform an otherwise abstract idea into patent-eligible subject matter."); *Planet Bingo*, 576 F. App'x at 1008 (finding claims abstract despite inclusion of "'a computer with a central processing unit,' 'a memory,' 'an input and output terminal,' 'a printer,' in some cases 'a video screen,' and 'a program . . . enabling.'").

The dependent claims of the '531 Patent all relate to the storage, transmission, and analysis of information using conventional computer components in conventional ways. Thus, the dependent claims provide no inventive elements sufficient to transform the abstract independent claims into patent eligible applications. *See, e.g.*, *Smart Sys. Innovations*, 873 F.3d at 1372 ("We have determined that claims directed to the collection, storage, and recognition of data are directed to an abstract idea.").

Thus, the claims of the '531 Patent are invalid because they claim unpatentable subject matter.

VIII. CONCLUSION

The asserted claims of the REMS Patents fail to claim patentable subject matter under 35 U.S.C. § 101 and are thus invalid. For the foregoing reasons, Defendants respectfully request that the Court grants Defendants' motion to dismiss under Rule 12(c) of the Federal Rules of Civil Procedure.

Respectfully submitted,

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